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MS: PCT

Attorney Docket No.: 27230U

Date: May 11, 2006

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re Application of:

FUCHSS

Art Unit: Unknown

Examiner: Unknown

Appl. No.: 10/573,203

Filed: March 24, 2006

Intl. Appl. No.: PCT/EP2004/052370

Intl. Filing Date: September 30, 2004

For: **IMIDAZO(4,5-B)PYRIDINE-DERIVATIVES AS INDUCIBLE NO-SYNTHASE INHIBITORS**

**TRANSMITTAL LETTER**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, Virginia 22313-1450

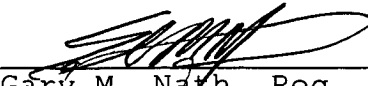
Sir:

Submitted herewith for filing in the U.S. Patent and Trademark Office is the following:

- 1) Submission of Documents to Supplement Filing Documents under 35 USC 371;
- 2) PCT/IB/373 (International Preliminary Report on Patentability);
- 3) PCT/ISA/237 (Written Opinion of the International Searching Authority).

The Commissioner is hereby authorized to charge any deficiency or credit any excess to Deposit Account Number 14-0112.

Respectfully submitted,  
**NATH & ASSOCIATES PLLC**

  
\_\_\_\_\_  
Gary M. Nath, Reg. No. 26,965  
Sheldon M. McGee, Reg. No. 50,454  
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NATH & ASSOCIATES PLLC  
112 South West Street  
Alexandria, VA 22314

GMN/SMM/1e



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**SUBMISSION OF DOCUMENTS**

**TO SUPPLEMENT FILING DOCUMENTS UNDER 35 USC 371**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450


Sir:

In order to supplement the filing documents for the national phase filing Under USC 371 commenced on **March 24, 2006** of the captioned application, applicant now submits the following documents:

- 1) PCT/IB/373 (International Preliminary Report on Patentability);
- 2) PCT/ISA/237 (Written Opinion of the International Searching Authority).

Please charge any deficiency or credit any overpayment to our Deposit Account Number 14-0112.

Respectfully submitted,  
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# PATENT COOPERATION TREATY

# PCT

## INTERNATIONAL PRELIMINARY REPORT ON PATENTABILITY

(Chapter I of the Patent Cooperation Treaty)

(PCT Rule 44bis)

Applicant's or agent's file reference 1143WOORD01	<b>FOR FURTHER ACTION</b>		See item 4 below
International application No. PCT/EP2004/052370	International filing date ( <i>day/month/year</i> ) 30 September 2004 (30.09.2004)	Priority date ( <i>day/month/year</i> ) 01 October 2003 (01.10.2003)	
International Patent Classification (8th edition unless older edition indicated) See relevant information in Form PCT/ISA/237			
Applicant ALTANA PHARMA AG			

1. This international preliminary report on patentability (Chapter I) is issued by the International Bureau on behalf of the International Searching Authority under Rule 44 bis.1(a).

2. This REPORT consists of a total of 7 sheets, including this cover sheet.

In the attached sheets, any reference to the written opinion of the International Searching Authority should be read as a reference to the international preliminary report on patentability (Chapter I) instead.

3. This report contains indications relating to the following items:

- |   |   |
|---|---|
| <input checked="" type="checkbox"/> Box No. I   | Basis of the report   |
| <input checked="" type="checkbox"/> Box No. II  | Priority  |
| <input checked="" type="checkbox"/> Box No. III | Non-establishment of opinion with regard to novelty, inventive step and industrial applicability  |
| <input type="checkbox"/> Box No. IV             | Lack of unity of invention  |
| <input checked="" type="checkbox"/> Box No. V   | Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement |
| <input type="checkbox"/> Box No. VI             | Certain documents cited   |
| <input type="checkbox"/> Box No. VII            | Certain defects in the international application  |
| <input type="checkbox"/> Box No. VIII           | Certain observations on the international application   |

4. The International Bureau will communicate this report to designated Offices in accordance with Rules 44bis.3(c) and 93bis.1 but not, except where the applicant makes an express request under Article 23(2), before the expiration of 30 months from the priority date (Rule 44bis .2).

Date of issuance of this report  
03 April 2006 (03.04.2006)

Authorized officer

Yolaine Cussac

Telephone No. +41 22 338 70 80

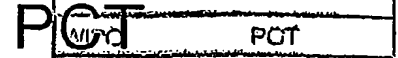
The International Bureau of WIPO  
34, chemin des Colombettes  
1211 Geneva 20, Switzerland

Facsimile No. +41 22 740 14 35

# PATENT COOPERATION TREATY

From the  
INTERNATIONAL SEARCHING AUTHORITY

REC'D 02 DEC 2004



To:

see form PCT/ISA/220

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**  
(PCT Rule 43bis.1)

Date of mailing  
(day/month/year) see form PCT/ISA/210 (second sheet)

Applicant's or agent's file reference  
see form PCT/ISA/220

**FOR FURTHER ACTION**  
See paragraph 2 below

International application No.  
PCT/EP2004/052370

International filing date (day/month/year)  
30.09.2004

Priority date (day/month/year)  
01.10.2003

International Patent Classification (IPC) or both national classification and IPC  
C07D471/04, A61K31/437, A61K31/444, A61P25/00, A61P29/00, A61P31/00

Applicant  
ALTANA PHARMA AG

1. This opinion contains indications relating to the following items:

- ☒ Box No. I Basis of the opinion
- ☒ Box No. II Priority
- ☒ Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability
- ☐ Box No. IV Lack of unity of invention
- ☒ Box No. V Reasoned statement under Rule 43bis.1 (a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement
- ☐ Box No. VI Certain documents cited
- ☐ Box No. VII Certain defects in the international application
- ☐ Box No. VIII Certain observations on the international application

2. **FURTHER ACTION**

If a demand for international preliminary examination is made, this opinion will usually be considered to be a written opinion of the International Preliminary Examining Authority ("IPEA"). However, this does not apply where the applicant chooses an Authority other than this one to be the IPEA and the chosen IPEA has notified the International Bureau under Rule 66.1bis(b) that written opinions of this International Searching Authority will not be so considered.

If this opinion is, as provided above, considered to be a written opinion of the IPEA, the applicant is invited to submit to the IPEA a written reply together, where appropriate, with amendments, before the expiration of three months from the date of mailing of Form PCT/ISA/220 or before the expiration of 22 months from the priority date, whichever expires later.

For further options, see Form PCT/ISA/220.

3. For further details, see notes to Form PCT/ISA/220.

Name and mailing address of the ISA:



European Patent Office - P.B. 5818 Patentlaan 2  
NL-2280 HV Rijswijk - Pays Bas  
Tel. +31 70 340 - 2040 Tx: 31 651 epo nl  
Fax: +31 70 340 - 3016

Authorized Officer

Bosma, P

Telephone No. +31 70 340-3665



**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2004/052370

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**Box No. I Basis of the opinion**

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1. With regard to the **language**, this opinion has been established on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.  
☐ This opinion has been established on the basis of a translation from the original language into the following language , which is the language of a translation furnished for the purposes of international search (under Rules 12.3 and 23.1(b)).
2. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application and necessary to the claimed invention, this opinion has been established on the basis of:
  - a. type of material:  
☐ a sequence listing  
☐ table(s) related to the sequence listing
  - b. format of material:  
☐ in written format  
☐ in computer readable form
  - c. time of filing/furnishing:  
☐ contained in the international application as filed.  
☐ filed together with the international application in computer readable form.  
☐ furnished subsequently to this Authority for the purposes of search.
3. ☐ In addition, in the case that more than one version or copy of a sequence listing and/or table relating thereto has been filed or furnished, the required statements that the information in the subsequent or additional copies is identical to that in the application as filed or does not go beyond the application as filed, as appropriate, were furnished.
4. Additional comments:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2004/052370

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**Box No. II    Priority**

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1. ☒ The following document has not been furnished:

☒ copy of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(a)).

☐ translation of the earlier application whose priority has been claimed (Rule 43*bis*.1 and 66.7(b)).

Consequently it has not been possible to consider the validity of the priority claim. This opinion has nevertheless been established on the assumption that the relevant date is the claimed priority date.

2. ☐ This opinion has been established as if no priority had been claimed due to the fact that the priority claim has been found invalid (Rules 43*bis*.1 and 64.1). Thus for the purposes of this opinion, the international filing date indicated above is considered to be the relevant date.

3. Additional observations, if necessary:

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2004/052370

**Box No. III Non-establishment of opinion with regard to novelty, inventive step and industrial applicability**

The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application,
- ☒ claims Nos. 10, 11 with respect of IA

because:

- ☒ the said international application, or the said claims Nos. 10, 11 with respect of IA relate to the following subject matter which does not require an international preliminary examination (*specify*):

**see separate sheet**

- ☐ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. are so unclear that no meaningful opinion could be formed (*specify*):
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the whole application or for said claims Nos.
- ☐ the nucleotide and/or amino acid sequence listing does not comply with the standard provided for in Annex C of the Administrative Instructions in that:
  - the written form ☐ has not been furnished
  - ☐ does not comply with the standard
  - the computer readable form ☐ has not been furnished
  - ☐ does not comply with the standard
- ☐ the tables related to the nucleotide and/or amino acid sequence listing, if in computer readable form only, do not comply with the technical requirements provided for in Annex C-*bis* of the Administrative Instructions.
- ☐ See separate sheet for further details

**WRITTEN OPINION OF THE  
INTERNATIONAL SEARCHING AUTHORITY**

International application No.  
PCT/EP2004/052370

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**Box No. V Reasoned statement under Rule 43bis.1(a)(i) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement**

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**1. Statement**

Novelty (N)	Yes: Claims	1-11
	No: Claims	
Inventive step (IS)	Yes: Claims	1-11
	No: Claims	
Industrial applicability (IA)	Yes: Claims	1-9
	No: Claims	

**2. Citations and explanations**

**see separate sheet**



**Re Item III.**

Claims 10 and 11 relate to subject-matter considered by this Authority to be covered by the provisions of Rule 67.1(iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject-matter of these claims (Article 34(4)(a)(I) PCT).

**Re Item V.**

The following documents are referred to in this communication:

D1 : WO 00/49015 A (TAKE KAZUHIKO ;FUJISAWA PHARMACEUTICAL CO (JP);  
TOMISHIMA MASAKI () 24 August 2000 (2000-08-24)

a) D1 describes compounds having a substituted pyridinemethyl moiety attached to eg a **benzoimidazolyl** group, which compounds are useful as nitric oxide synthase inhibitors, from which the compounds of the present application mainly differ in having a 4-alkoxypyridin-2-yl-ethylene moiety attached to a **imidazo[4,5-b]pyridine** group in which the ethylene group is substituted by R1,R11, and are also useful as nitric oxide synthase inhibitors.

Therefore the present application satisfies the criterion set forth in Article 33(2) PCT and is considered to be new in respect of the prior art.

b) The problem to be solved by the present application is to provide further compounds, which are useful as nitric oxide synthase inhibitors. This problem has been solved by the specific substituted 4-alkoxypyridin-2-yl-ethylene-imidazo[4,5-b]pyridine derivatives of formula (I) of the present application. From the available prior art there were no incentives to use the above mentioned type of compounds as nitric oxide synthase inhibitors.. The present application consequently satisfies the criterion set forth in Article 33(3) PCT, because the subject-matter of claims 1-11 is considered to be not obvious and to involve an inventive step.

**Industrial applicability**

The present compounds are useful as nitric oxide synthase inhibitors.

For the assessment of the present claims 10 and 11 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.